

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK**

ANA TRASTOY,

Plaintiff,

Civil Action No.: 08-CV-4158

vs.

MERCK & CO., INC.,

Defendant.

COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiff, ANA TRASTOY, through her undersigned attorneys, ASHCRAFT & GERE, LLP, sues Defendant Merck & Company, Inc., and alleges as follows:

I. JURISDICTION AND VENUE

1. This Court has jurisdiction pursuant to 28 U.S.C. §§1332, as complete diversity exists between Plaintiff and Defendant. Plaintiff is a resident of the state of New York, and Defendant is incorporated and has its primary place of business in the state of New Jersey. The amount in controversy, exclusive of interest and costs, exceeds \$75,000.
2. Venue is proper within this district pursuant to Case Management Order No. 3, filed November 1, 2006, signed by John F. Keenan, allowing Fosamax-related cases to be filed directly in the Southern District of New York.

II. PARTIES

3. Plaintiff Ana Trastoy was born December 18, 1930. At all relevant times Plaintiff was a resident of the state of New York, and used FOSAMAX from approximately

1995 through approximately August of 2007.

4. Defendant is a corporation organized and existing under the laws of the state of New Jersey, with its principal place of business in New Jersey. The Defendant's registered office is at 820 Bear Tavern Road, City of West Trenton, Mercer County, New Jersey.
5. Defendant was at all relevant times authorized to conduct business in the state of New York.
6. At all times relevant Defendant regularly transacted business in the state of New York and continues to do so.
7. At all relevant times Defendant, through its agents, servants, employees and apparent agents was the designer, manufacturer, marketer, distributor and seller of FOSAMAX, a bisphosphonate drug used primarily to mitigate or reverse the effects of osteoporosis.
8. Defendant, either directly or through its agents, apparent agents, servants or employees, at all relevant times, sold and distributed FOSAMAX in the state of New York for the treatment or prevention of osteoporosis, Paget's Disease and other off-label uses.
9. Defendant derives substantial revenue from pharmaceutical products used or consumed in the state of New York.
10. Defendant expected, or should have expected, that its business activities could or would have consequences within the state of New York.

III. SUMMARY OF THE CASE

11. Defendant, either directly or through its agents, apparent agents, servants or employees designed, manufactured, marketed, advertised, distributed and sold FOSAMAX for the treatment of osteoporosis, Paget's Disease, and other off-label uses.
12. As a result of the defective nature of FOSAMAX, persons who were prescribed and ingested FOSAMAX, including Plaintiff Ana Trastoy, have suffered and may continue to suffer severe and permanent personal injuries to the jaw bone, including osteonecrosis of the jaw and other diagnoses of irreversible damage to the jaw.
13. Defendant concealed its knowledge of FOSAMAX's unreasonably dangerous risks from Plaintiff Ana Trastoy, other consumers, and the medical community.
14. Defendant failed to conduct adequate and sufficient post-marketing surveillance of FOSAMAX after it began marketing, advertising, distributing, and selling the drug.
15. As a result of Defendant's actions and inaction, Plaintiff Ana Trastoy was injured due to her ingestion of FOSAMAX, which has caused and will continue to cause Plaintiff's various injuries and damages. Plaintiff accordingly seeks compensatory damages.

IV. FACTUAL BACKGROUND

16. At all relevant times Defendant was responsible for, or involved in, designing, manufacturing, marketing, advertising, distributing, and selling FOSAMAX.
17. In September 1995, the United States Food and Drug Administration ("FDA")

approved Merck's compound alendronate, which is marketed by Merck as FOSAMAX, for various uses, including the treatment of osteoporosis and Paget's Disease.

18. FOSAMAX falls within a class of drugs known as bisphosphonates. Bisphosphonates are used for treating bone conditions such as osteoporosis and Paget's disease. Other drugs within this class such as Aredia and Zometa are also used as chemotherapy and as adjunct chemotherapy but are not indicated for use in non-cancerous conditions such as osteoporosis.
19. There are two classes of bisphosphonates: the N-containing (nitrogenous) and non-N-containing (non-nitrogenous) bisphosphonates. The nitrogenous bisphosphonates include the following: pamidronate (Aredia); ibandronate (Boniva); risedronate (Actonel); and alendronate (FOSAMAX). The non-nitrogenous bisphosphonates include the following: etridonate (Didronel); clodronate (Bonefos and Loron); and tiludronate (Skelid). Alendronate, like the others, contains a nitrogen atom, whereas etridonate, clodronate, and tiludronate do not. The PDR for FOSAMAX confirms that the molecule contains a nitrogen atom.
20. Throughout the 1990s and 2000s, medical articles and studies appeared reporting the frequent and common occurrence of osteonecrosis of the jaw within the nitrogenous bisphosphonates used for chemotherapy. As with its reported and acknowledged side effects concerning irritation, erosion, and inflammation of the upper gastrointestinal tract, Merck knew or should have known that FOSAMAX, as a nitrogenous

bisphosphonate, shared a similar adverse event profiles to the other drugs within this specific subclass of bisphosphonates (i.e., those containing nitrogen).

21. Merck knew and or should have known that bisphosphonates, including FOSAMAX, inhibit endothelial cell function. Similarly, Merck knew or should have known that bisphosphonates also inhibit vascularization of the affected area and induce ischemic changes specific to patients mandibles (lower jaws) and maxillae (upper jaws) and that these ischemic changes appear to be cumulative in nature.
22. Merck also knew or should have known that these factors combine to create a compromised vascular supply in the affected area. As a result, a minor injury or disease can turn into a non-healing wound. That in turn can progress to widespread necrosis (bone death) and osteomyelitis (inflammation of bone marrow).
23. Dentists are now being advised by state dental associations to refrain from using any invasive procedure (such as drilling a cavity) for any patient on FOSAMAX.
24. Once the osteonecrosis begins and becomes symptomatic, it is very difficult to treat and is not reversible.
25. Shortly after Defendant began selling FOSAMAX, reports of osteonecrosis of the jaw and other dental complications among users began surfacing, indicating that FOSAMAX shared the class effects of the other nitrogenous bisphosphonates. Despite this knowledge, Defendant failed to implement further study risk of osteonecrosis of the jaw relative to FOSAMAX. Rather than evaluating and verifying the safety of FOSAMAX with respect to osteonecrosis of the jaw,

Defendant proposed further uses of FOSAMAX, such as FOSAMAX-D, and sought to extend the exclusivity period of FOSAMAX through 2018.

26. Osteonecrosis of the jaw is a serious medical event and can result in severe disability and death.
27. Since FOSAMAX was released, the FDA has received a number of reports osteonecrosis of the jaw among users of FOSAMAX.
28. On August 25, 2004, the FDA posted its ODS (Office of Drug Safety) Postmarketing Safety Review on bisphosphonates -- specifically pamidronate (Aredia), zoledronic acid (Zometa), risedronate (Actonel), and alendronate (FOSAMAX). This was an epidemiologic review of the FDA adverse events database conducted by the FDA's Division of Drug Risk Evaluation.
29. As a result of the FDA Review, the FDA observed that the risk of osteonecrosis of the jaw was not confined to bisphosphonates used for chemotherapy. The FDA's review indicated that the osteonecrosis of the jaw was a class effect which specifically extended to the oral bisphosphonate, FOSAMAX.
30. As a result, the FDA recommended and stated that the labeling for FOSAMAX should be amended by Merck to specifically warn about the risk of osteonecrosis of the jaw. Merck has refused to accede to the FDA's request and, to this day, still does not warn of the risk of osteonecrosis of the jaw in its FOSAMAX labeling.
31. Rather than warn patients, and despite knowledge known by Defendant about increased risk of osteonecrosis of the jaw in patients using FOSAMAX, Defendant

continues to defend FOSAMAX and minimize unfavorable findings.

32. FOSAMAX is one of Defendant's top selling drugs. Averaging more than \$3 billion a year in sales.

33. Consumers, including Plaintiff Ana Trastoy, who have used FOSAMAX for the treatment or prevention of osteoporosis, Paget's Disease and/or other off-label uses, have several alternative safer products available to treat their conditions.

34. Defendant knew of the significant risk of dental and oral complications caused by ingestion of FOSAMAX, but Defendant did not adequately and sufficiently warn consumers, including Plaintiff Ana Trastoy, or the medical community, of such risks.

35. In the design, manufacture, labeling, and marketing of FOSAMAX, the Defendants engaged in numerous acts that constituted violations of federal statutes and regulations, including but not limited to:

- a. The labeling lacked adequate information on the use of the drug Fosamax® (21 C.F.R. Section 201.56(a) and (d));
- b. The labeling failed to provide adequate warnings of severe and disabling medical conditions including, without limitation, osteonecrosis of the jaw, and other adverse medical conditions as soon as there was reasonable evidence of their association with the drug (21 C.F.R. 201.57(e));
- c. There was inadequate information for patients for the safe and effective use of Defendant's drug (21 C.F.R 201.57(f)(2));
- d. There was inadequate information regarding special care to be exercised by the Plaintiff's doctors for safe and effective use of Defendant's drug (21 C.F.R. 201.57(f)(1));
- e. The labeling was misleading and promotional (21 C.F.R. 201.56(b));

and

- f. Defendant's acts constitute an adulteration and/or misbranding as defined by the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 331.

36. As a direct result, Plaintiff Ana Trastoy was prescribed FOSAMAX and has been permanently and severely injured, having suffered serious consequences from the ingestion of FOSAMAX. Plaintiff Ana Trastoy requires and will in the future require ongoing medical care and treatment for the injuries she suffered as a result of taking FOSAMAX.

37. Plaintiff Ana Trastoy has suffered from mental anguish from the knowledge that she will have life-long complications as a result of the injuries Plaintiff sustained from the use of FOSAMAX.

38. Plaintiff Ana Trastoy was prescribed and began taking FOSAMAX in 1995. She was diagnosed with osteonecrosis of the jaw on or about August of 2007.

39. Plaintiff used FOSAMAX as prescribed and in a foreseeable manner.

40. As a direct and proximate result of using FOSAMAX, Plaintiff suffered severe personal injury.

41. Plaintiff, as a direct and proximate result of using FOSAMAX, suffered severe mental and physical pain and suffering and has sustained permanent injuries and emotional distress.

42. Plaintiff used FOSAMAX which had been provided to her in a condition that was substantially the same as the condition in which it was manufactured and sold.

43. Plaintiff would not have used FOSAMAX had Defendant properly disclosed the risks associated with the drug. Alternatively, Plaintiff would have known the precursor events of osteonecrosis of the jaw and would have been able to avoid the clinical manifestation of the symptoms as they currently exist.
44. Defendant, through its affirmative misrepresentations and omissions, actively concealed from Plaintiff and her physicians the true and significant risks associated with taking FOSAMAX. The running of any applicable statute of limitations has been tolled by reason of Defendant's fraudulent concealment.
45. As a result of Defendant's actions, Plaintiff and her prescribing physicians were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks identified in this complaint, and that those risks were the direct and proximate result of Defendant's acts, omissions, and misrepresentations.

V. COUNTS

COUNT I: NEGLIGENCE

46. Plaintiff re-alleges the above paragraphs as if fully set forth herein.
47. Defendant owed Plaintiff, Ana Trastoy, and other consumers, a duty to exercise reasonable care when designing, manufacturing, marketing, advertising, distributing, and selling FOSAMAX.
48. Defendant failed to exercise due care under the circumstances and therefore breached this duty by:

- a. failing to properly and thoroughly test FOSAMAX before releasing the drug to market;
- b. failing to properly and thoroughly analyze the data resulting from the pre-marketing tests of FOSAMAX;
- c. failing to conduct sufficient post-market testing and surveillance of FOSAMAX;
- d. designing, manufacturing, marketing, advertising, distributing, and selling FOSAMAX to consumers, including Plaintiff, without an adequate warning of the significant and dangerous risks of FOSAMAX and without proper instructions to avoid the harm which could foreseeably occur as a result of using the drug;
- e. failing to exercise due care when advertising and promoting FOSAMAX; and
- f. negligently continuing to manufacture, market, advertise, and distribute FOSAMAX after Defendant knew or should have known of its adverse effects.

49. As a direct and proximate consequence of Defendant's actions, omissions, and misrepresentations, Plaintiff Ana Trastoy sustained significant and permanent injury to her jaw. In addition, Plaintiff required and will continue to require healthcare and services as a result of the injury suffered. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage-earning capacity.

50. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.
51. The Plaintiffs' allegations in this Count include breaches of duties that are parallel to the requirements set forth in the numerous federal statutes and regulations which were violated by the Defendant.

COUNT II: STRICT LIABILITY

52. Plaintiff re-alleges the above paragraphs as if fully set forth herein.
53. Defendant manufactured, sold, distributed, marketed, and/or supplied FOSAMAX in a defective and unreasonably dangerous condition to consumers, including Plaintiff Ana Trastoy.
54. Defendant designed, manufactured, sold, distributed, supplied, marketed, and/or promoted FOSAMAX, which was expected to reach and did in fact reach consumers, including Plaintiff, without substantial change in the condition in which it was manufactured and sold by Defendant.
55. Plaintiff used FOSAMAX as prescribed and in a manner normally intended, recommended, promoted, and marketed by Defendant.
56. FOSAMAX failed to perform safely when used by ordinary consumers, including Plaintiff, including when it was used as intended and in a reasonably foreseeable

manner.

57. FOSAMAX was defective in its design and was unreasonably dangerous in that its unforeseeable risks exceeded the benefits associated with its design or formulation.

58. FOSAMAX was defective in design or formulation in that it posed a greater likelihood of injury than other similar medications and was more dangerous than an ordinary consumer could reasonably foresee or anticipate.

59. FOSAMAX was defective in its design and was unreasonably dangerous in that it neither bore nor was packaged with nor accompanied by warnings adequate to alert consumers, including Plaintiff, of the risks described herein, including, but not limited to, the risk of osteonecrosis of the jaw.

60. Although Defendant knew or should have known of the defective nature of FOSAMAX, it continued to design, manufacture, market, and sell FOSAMAX so as to maximize sales and profits at the expense of the public health and safety. By so acting, Defendant acted with conscious and deliberate disregard of the foreseeable harm caused by FOSAMAX.

61. Plaintiff could not, through the exercise of reasonable care, have discovered FOSAMAX's defects or perceived the dangers posed by the drug.

62. As a direct and proximate consequence of Defendant's conduct, Plaintiff Ana Trastoy sustained significant and permanent injury of the jaw. In addition, Plaintiff required and will continue to require healthcare and services as a result of the injury suffered.

Plaintiff has incurred and will continue to incur medical and related expenses as a result of her injury. Plaintiff has also suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage-earning capacity.

63. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.
64. The Plaintiffs' allegations in this Count include breaches of duties that are parallel to the requirements set forth in the numerous federal statutes and regulations which were violated by the Defendant.

COUNT III: BREACH OF EXPRESS WARRANTY

65. Plaintiff re-alleges the above paragraphs as if fully set forth herein.
66. Defendant expressly represented to Plaintiff Ana Trastoy, other consumers and the medical community that FOSAMAX was safe and fit for its intended purposes, was of merchantable quality, did not produce any dangerous side effects, and had been

adequately tested.

67. FOSAMAX does not conform to Defendant's express representations because it is not safe, has numerous and serious side effects, and causes severe and permanent injuries.

68. At all relevant times FOSAMAX did not perform as safely as an ordinary consumer would expect, when used as intended or in a reasonably foreseeable manner.

69. Plaintiff Ana Trastoy, other consumers, and the medical community relied upon Defendant's express warranties.

70. As a direct and proximate result of Defendant's actions, Plaintiff Ana Trastoy sustained significant and permanent injury of the jaw. In addition, Plaintiff required and will continue to require healthcare and services as a result of the injury suffered. Plaintiff has incurred and will continue to incur medical and related expenses as a result of her injury. Plaintiff has also suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage-earning capacity.

71. Defendant's conduct as described above was committed with knowing, conscious,

wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

72. The Plaintiffs' allegations in this Count include breaches of duties that are parallel to the requirements set forth in the numerous federal statutes and regulations which were violated by the Defendant.

COUNT IV: BREACH OF IMPLIED WARRANTY

73. Plaintiff re-alleges the above paragraphs as if fully set forth herein.
74. Defendant manufactured, distributed, advertised, promoted, and sold FOSAMAX.
75. At all relevant times, Defendant knew of the use for which FOSAMAX was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.
76. Defendant was aware that consumers, including Plaintiff Ana Trastoy, would use FOSAMAX for treatment or prevention of osteoporosis or Paget's Disease and for other off-label purposes.
77. Plaintiff and the medical community reasonably relied upon the judgment and sensibility of Merck to sell FOSAMAX only if it was indeed of merchantable quality and safe and fit for its intended use.
78. Defendant breached its implied warranty to consumers, including Plaintiff; FOSAMAX was not of merchantable quality or safe and fit for its intended use.

79. Consumers, including Plaintiff, and the medical community, reasonably relied upon Defendant's implied warranty for FOSAMAX.
80. FOSAMAX reached consumers without substantial change in the condition in which it was manufactured and sold by Defendant.
81. As a direct and proximate result of Defendant's action, Plaintiff Ana Trastoy sustained significant and permanent injury of the jaw. In addition, Plaintiff required and will continue to require healthcare and services as a result of the injury suffered. Plaintiff has incurred and will continue to incur medical and related expenses as a result of her injury. Plaintiff has also suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage-earning capacity.
82. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.
83. The Plaintiffs' allegations in this Count include breaches of duties that are parallel

to the requirements set forth in the numerous federal statutes and regulations which were violated by the Defendant.

COUNT V: FRAUDULENT MISREPRESENTATION

84. Plaintiff re-alleges the above paragraphs as if fully set forth herein.
85. Defendant made fraudulent misrepresentations with respect to FOSAMAX in the following particulars:
 - a. Defendant represented through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that FOSAMAX had been tested and found to be safe and effective for the treatment of osteoporosis and Paget's Disease; and
 - b. Defendant represented that FOSAMAX was safer than other alternative medications.
86. Defendant knew that its representations were false, yet it willfully, wantonly, and recklessly disregarded its obligation to provide truthful representations regarding the safety and risk of FOSAMAX to consumers, including Plaintiff, and the medical community.
87. The representations were made by Defendant with the intent that doctors and patients, including Plaintiff, rely upon them.
88. Defendant's representations were made with the intent of defrauding and deceiving Plaintiff, other consumers, and the medical community to induce and encourage the sale of FOSAMAX.
89. Plaintiff Ana Trastoy, Plaintiff's doctors, and others relied upon the representations.

90. Defendant's fraudulent representations evinced its callous, reckless, willful, and depraved indifference to the health, safety, and welfare of consumers, including Plaintiff.

91. As a direct and proximate result, Plaintiff Ana Trastoy sustained significant and permanent injury to her jaw. In addition, as a result of her injury, Plaintiff required and will continue to require healthcare and services, and has incurred and will continue to incur medical and related expenses. Plaintiff also suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage-earning capacity.

92. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

93. The Plaintiffs' allegations in this Count include breaches of duties that are parallel to the requirements set forth in the numerous federal statutes and regulations which were violated by the Defendant.

COUNT VI: FRAUDULENT CONCEALMENT

94. Plaintiff re-alleges the above paragraphs as if fully set forth herein.
95. Defendant fraudulently concealed information with respect to FOSAMAX in the following particulars:
 - a. Defendant represented through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that FOSAMAX was safe and fraudulently withheld and concealed information about the substantial risks of using FOSAMAX; and
 - b. Defendant represented that FOSAMAX was safer than other alternative medications and fraudulently concealed information which demonstrated that FOSAMAX was not safer than alternatives available on the market.
96. Defendant had sole access to material facts concerning the dangers and unreasonable risks associated with FOSAMAX.
97. Defendant's concealment of information about the risks associated with taking FOSAMAX was intentional, and the representations made by Defendant were known by Defendant to be false.
98. The concealment of information and the misrepresentations about FOSAMAX were made by Defendant with the intent that doctors and patients, including Plaintiff, rely upon them.
99. Plaintiff Ana Trastoy, Plaintiff's doctors, and others relied upon the representations and were unaware of the substantial dental and oral risks associated with taking FOSAMAX that Defendant had concealed from them.
100. As a direct and proximate result of Defendant's fraudulent concealment and

misrepresentations, Plaintiff Ana Trastoy sustained significant and permanent injury of the jaw. In addition, Plaintiff required and will continue to require healthcare and services as a result of the injury suffered. Plaintiff has incurred and will continue to incur medical and related expenses as a result of her injury. Plaintiff has also suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage-earning capacity.

101. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.
102. The Plaintiffs' allegations in this Count include breaches of duties that are parallel to the requirements set forth in the numerous federal statutes and regulations which were violated by the Defendant.

GLOBAL PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendant, as follows:

- a. compensatory damages on each cause of action;
- b. punitive damages on each cause of action;
- c. reasonable attorneys' fees where recoverable;
- d. costs of this action; and
- e. such other additional and further relief as the Court may deem necessary, appropriate, and just.

VI. DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury on all counts and issues so triable.

ASHCRAFT & GEREL, LLP



Michelle A. Parfitt, Esq.

(Order granting admission *pro hac vice* for MDL 1789 is attached)

2000 L Street, N.W., Suite 400
Washington, DC 20036
Telephone: (202) 783-6400
Fax: (202) 416-6392

Attorneys for Plaintiffs

JS 44C/SDNY
REV. 12/2005

CIVIL COVER SHEET

The JS-44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for use of the Clerk of Court for the purpose of initiating the civil docket sheet.

PLAINTIFFS ANA TRASTOY

DEFENDANTS MERCK & CO., INC.

ATTORNEYS (FIRM NAME, ADDRESS, AND TELEPHONE NUMBER) ATTORNEYS (IF KNOWN)

ASHCRAFT & GEREL, LLP, 2000 L STREET, NW
SUITE 400, WASHINGTON, DC 20036
Michelle A. Parfitt

CAUSE OF ACTION (CITE THE U.S. CIVIL STATUTE UNDER WHICH YOU ARE FILING AND WRITE A BRIEF STATEMENT OF CAUSE)

28 U.S.C. 1332
PRODUCT LIABILITY - DEFECTIVE PHARMACEUTICAL (Fosamax)Has this or a similar case been previously filed in SDNY at any time? No Yes? Judge Previously Assigned KEENANIf yes, was this case Vol Invol. Dismissed. No Yes If yes, give date _____ & Case No. _____(PLACE AN IN ONE BOX ONLY)

NATURE OF SUIT

ACTIONS UNDER STATUTES

CONTRACT	PERSONAL INJURY	PERSONAL INJURY	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
<input type="checkbox"/> 110 INSURANCE	<input type="checkbox"/> 310 AIRPLANE	<input type="checkbox"/> 362 PERSONAL INJURY - MED MALPRACTICE	<input type="checkbox"/> 610 AGRICULTURE	<input type="checkbox"/> 422 APPEAL	<input type="checkbox"/> 400 STATE REAPPORTIONMENT
<input type="checkbox"/> 120 MARINE	<input type="checkbox"/> 315 AIRPLANE PRODUCT LIABILITY	<input type="checkbox"/> 365 PERSONAL INJURY PRODUCT LIABILITY	<input type="checkbox"/> 620 FOOD & DRUG	<input type="checkbox"/> 28 USC 158	<input type="checkbox"/> 410 ANTITRUST
<input type="checkbox"/> 130 MILLER ACT	<input type="checkbox"/> 320 ASSAULT, LIBEL & SLANDER	<input type="checkbox"/> 368 ASBESTOS PERSONAL INJURY PRODUCT LIABILITY	<input type="checkbox"/> 625 DRUG RELATED	<input type="checkbox"/> 423 WITHDRAWAL	<input type="checkbox"/> 430 BANKS & BANKING
<input type="checkbox"/> 140 NEGOTIABLE INSTRUMENT	<input type="checkbox"/> 330 FEDERAL EMPLOYERS' LIABILITY	<input type="checkbox"/> 630 LIQUOR LAWS	<input type="checkbox"/> 21 USC 881	<input type="checkbox"/> 28 USC 157	<input type="checkbox"/> 450 COMMERCE/ICC RATES/ETC
<input type="checkbox"/> 150 RECOVERY OF OVERPAYMENT & ENFORCEMENT OF JUDGMENT	<input type="checkbox"/> 340 MARINE LIABILITY	<input type="checkbox"/> 640 RR & TRUCK	<input type="checkbox"/> 640 PERSONAL PROPERTY	<input type="checkbox"/> 820 COPYRIGHTS	<input type="checkbox"/> 460 DEPORTATION
<input type="checkbox"/> 151 MEDICARE ACT	<input type="checkbox"/> 345 MARINE PRODUCT LIABILITY	<input type="checkbox"/> 650 AIRLINE REGS	<input type="checkbox"/> 650 PROPERTY LIABILITY	<input type="checkbox"/> 830 PATENT	<input type="checkbox"/> 470 RACKETEER INFLUENCED & CORRUPT ORGANIZATION ACT (RICO)
<input type="checkbox"/> 152 RECOVERY OF DEFANTED STUDENT LOANS (EXCL VETERANS)	<input type="checkbox"/> 350 MOTOR VEHICLE PRODUCT LIABILITY	<input type="checkbox"/> 660 OCCUPATIONAL SAFETY/HEALTH	<input type="checkbox"/> 660 OTHER	<input type="checkbox"/> 840 TRADEMARK	<input type="checkbox"/> 480 CONSUMER CREDIT
<input type="checkbox"/> 153 RECOVERY OF OVERPAYMENT OF VETERANS BENEFITS	<input type="checkbox"/> 355 MOTOR VEHICLE PRODUCT LIABILITY	<input type="checkbox"/> 670 OTHER		<input type="checkbox"/> 850 CABLE/SATELLITE TV	
<input type="checkbox"/> 160 STOCKHOLDERS SUITS	<input type="checkbox"/> 360 OTHER PERSONAL INJURY	<input type="checkbox"/> 680 OTHER		<input type="checkbox"/> 860 SELECTIVE SERVICE	
<input type="checkbox"/> 190 OTHER CONTRACT		<input type="checkbox"/> 690 OTHER		<input type="checkbox"/> 850 SECURITIES/ COMMODITIES/ EXCHANGE	
<input type="checkbox"/> 195 CONTRACT PRODUCT LIABILITY				<input type="checkbox"/> 875 CUSTOMER CHALLENGE	
<input type="checkbox"/> 196 FRANCHISE				<input type="checkbox"/> 12 USC 3410	
				<input type="checkbox"/> 891 AGRICULTURE ACTS	
				<input type="checkbox"/> 892 ECONOMIC STABILIZATION ACT	
				<input type="checkbox"/> 893 ENVIRONMENTAL MATTERS	
				<input type="checkbox"/> 894 ENERGY ALLOCATION ACT	
				<input type="checkbox"/> 895 FREEDOM OF INFORMATION ACT	
				<input type="checkbox"/> 900 APPEAL OF FEE DETERMINATION	
				<input type="checkbox"/> UNDER EQUAL ACCESS TO JUSTICE	
				<input type="checkbox"/> 950 CONSTITUTIONALITY OF STATE STATUTES	
				<input type="checkbox"/> 890 OTHER STATUTORY ACTIONS	
REAL PROPERTY	CIVIL RIGHTS	PRISONER PETITIONS	ACTIONS UNDER STATUTES		
<input type="checkbox"/> 210 LAND CONDEMNATION	<input type="checkbox"/> 441 VOTING	<input type="checkbox"/> 510 MOTIONS TO VACATE SENTENCE	<input type="checkbox"/> 791 EMPL RET INC SECURITY ACT	<input type="checkbox"/> 870 TAXES	
<input type="checkbox"/> 220 FORECLOSURE	<input type="checkbox"/> 442 EMPLOYMENT	<input type="checkbox"/> 28 USC 2255		<input type="checkbox"/> 871 IRS-THIRD PARTY	
<input type="checkbox"/> 230 RENT LEASE & EJECTMENT	<input type="checkbox"/> 443 HOUSING ACCOMMODATIONS	<input type="checkbox"/> 530 HABEAS CORPUS		<input type="checkbox"/> 20 USC 7609	
<input type="checkbox"/> 240 TORTS TO LAND	<input type="checkbox"/> 444 WELFARE	<input type="checkbox"/> 535 DEATH PENALTY			
<input type="checkbox"/> 246 TORT PRODUCT LIABILITY	<input type="checkbox"/> 445 AMERICANS WITH DISABILITIES - EMPLOYMENT	<input type="checkbox"/> 540 MANDAMUS & OTHER			
<input type="checkbox"/> 290 ALL OTHER REAL PROPERTY	<input type="checkbox"/> 446 AMERICANS WITH DISABILITIES - OTHER	<input type="checkbox"/> 550 CIVIL RIGHTS			
	<input type="checkbox"/> 440 OTHER CIVIL RIGHTS	<input type="checkbox"/> 555 PRISON CONDITION			

Check if demanded in complaint:

CHECK IF THIS IS A CLASS ACTION
UNDER F.R.C.P. 23DO YOU CLAIM THIS CASE IS RELATED TO A CIVIL CASE NOW PENDING IN S.D.N.Y.?
IF SO, STATE:

DEMAND \$ _____ OTHER _____ JUDGE KEENAN DOCKET NUMBER 06-MDL 1789

Check YES only if demanded in complaint

JURY DEMAND: YES NO

NOTE: Please submit at the time of filing an explanation of why cases are deemed related.

(SEE REVERSE)

(PLACE AN *x* IN ONE BOX ONLY)

ORIGIN

1 Original Proceeding 2a. Removed from 3 Remanded from 4 Reinstated or Reopened 5 Transferred from 6 Multidistrict Litigation 7 Appeal to District Judge from Magistrate Judge Judgment

2b. Removed from State Court
AND at least one party is a pro se litigant

(PLACE AN *x* IN ONE BOX ONLY)

BASIS OF JURISDICTION

IF DIVERSITY, INDICATE CITIZENSHIP BELOW.
(28 USC 1332, 1441)

1 U.S. PLAINTIFF 2 U.S. DEFENDANT 3 FEDERAL QUESTION 4 DIVERSITY
(U.S. NOT A PARTY)

CITIZENSHIP OF PRINCIPAL PARTIES (FOR DIVERSITY CASES ONLY)

(Place an [X] in one box for Plaintiff and one box for Defendant)

CITIZEN OF THIS STATE	PTF <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 1	DEF <input type="checkbox"/> 2 <input type="checkbox"/> 2	CITIZEN OR SUBJECT OF A FOREIGN COUNTRY	PTF <input type="checkbox"/> 3 <input checked="" type="checkbox"/> 3	DEF <input type="checkbox"/> 4 <input type="checkbox"/> 4	INCORPORATED and PRINCIPAL PLACE OF BUSINESS IN ANOTHER STATE	PTF <input type="checkbox"/> 5 <input checked="" type="checkbox"/> 5	DEF <input type="checkbox"/> 6 <input type="checkbox"/> 6
CITIZEN OF ANOTHER STATE	<input type="checkbox"/> 12	<input type="checkbox"/> 12	INCORPORATED or PRINCIPAL PLACE OF BUSINESS IN THIS STATE	<input type="checkbox"/> 14	<input type="checkbox"/> 14	FOREIGN NATION	<input type="checkbox"/> 16	<input type="checkbox"/> 16

PLAINTIFF(S) ADDRESS(ES) AND COUNTY(IES)

ANA TRASTOY
2651 OCEANSIDE ROAD
OCEANSIDE, NY 11572

DEFENDANT(S) ADDRESS(ES) AND COUNTY(IES)

MERCK & CO., INC.
ONE MERCK DRIVE
P.O. BOX 100, WS3AB-05
WHITEHOUSE STATION, NEW JERSEY, 08889-0100

DEFENDANT(S) ADDRESS UNKNOWN

REPRESENTATION IS HEREBY MADE THAT, AT THIS TIME, I HAVE BEEN UNABLE, WITH REASONABLE DILIGENCE, TO ASCERTAIN THE RESIDENCE ADDRESSES OF THE FOLLOWING DEFENDANTS:

Check one: THIS ACTION SHOULD BE ASSIGNED TO: WHITE PLAINS FOLEY SQUARE
(DO NOT check either box if this a PRISONER PETITION.)

DATE SIGNATURE OF ATTORNEY OF RECORD

ADMITTED TO PRACTICE IN THIS DISTRICT

RECEIPT #

NO
 YES (DATE ADMITTED Mo. 4 Yr. 2008)
Attorney Bar Code # XXXXX

Magistrate Judge is to be designated by the Clerk of the Court.

Magistrate Judge _____ is so Designated.

J Michael McMahon, Clerk of Court by _____ Deputy Clerk, DATED _____.

UNITED STATES DISTRICT COURT (NEW YORK SOUTHERN)

United States District Court

SOUTHERN

DISTRICT OF

NEW YORK

ANA TRASTOY

SUMMONS IN A CIVIL CASE**V.**

CASE NUMBER:

MERCK & CO., INC.

TO: (Name and address of defendant)

MERCK & CO., INC.
C/O C T CORPORATION SYSTEM
111 EIGHTH AVENUE
NEW YORK, NEW YORK, 10011

YOU ARE HEREBY SUMMONED and required to serve upon PLAINTIFF'S ATTORNEY (name and address)

MICHELLE A. PARFITT, ESQ.
ASHCRAFT & GEREL, LLP
2000 L. STREET, N.W., SUITE 400
WASHINGTON, DC. 20036

an answer to the complaint which is herewith served upon you, within _____ days after service of this summons upon you, exclusive of the day of service. If you fail to do so, judgment by default will be taken against you for the relief demanded in the complaint. You must also file your answer with the Clerk of this Court within a reasonable period of time after service.

CLERK

DATE

(BY) DEPUTY CLERK

RETURN OF SERVICE		
Service of the Summons and Complaint was made by me ¹	DATE	
NAME OF SERVER (PRINT)	TITLE	
<i>Check one box below to indicate appropriate method of service</i>		
<input type="checkbox"/> Served personally upon the defendant. Place where served: _____ _____		
<input type="checkbox"/> Left copies thereof at the defendant's dwelling house or usual place of abode with a person of suitable age and discretion then residing therein. Name of person with whom the summons and complaint were left: _____ _____		
<input type="checkbox"/> Returned unexecuted: _____ _____		
<input type="checkbox"/> Other (specify): _____ _____		
STATEMENT OF SERVICE FEES		
TRAVEL	SERVICES	TOTAL
DECLARATION OF SERVER		
<p>I declare under penalty of perjury under the laws of the United States of America that the foregoing information contained in the Return of Service and Statement of Service Fees is true and correct.</p> <p>Executed on _____ Date _____</p> <p>Signature of Server _____</p> <p>Address of Server _____</p>		

(1) As to who may serve a summons see Rule 4 of the Federal Rules of Civil Procedure.

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK**

IN RE: Fosamax Products Liability
Litigation

1:06-MDL-1789 (JFK)

This Document Relates to:

MDL 1789

Civil No.:

USDC SDNY
DOCUMENT
ELECTRONICALLY FILED
DOC #: _____
DATE FILED: 4-24-08

ORDER FOR ADMISSION *PRO HAC VICE*

Upon consideration of the attached Certificate of Good Standing from the Clerk of Court
for the United States District Court for the District of Columbia, it is hereby ORDERED this

day of _____, 2008, that

Michelle A. Parfitt
Ashcraft & Gerel, LLP
2000 L Street, N.W., Suite 400
Washington, DC 20036
Telephone: (202) 783-6400
Fax: (202) 416-6392

is admitted to practice *pro hac vice* as counsel for the Plaintiffs in the above-referenced MDL
proceeding.

4/24/08 John F. Keenan
Judge John F. Keenan

MICROFILMED
APR 25 2008 -12 00 PM